APR 1 1 2001 K010757

Special 510(k) Summary - Addition of V40™ Femoral Head Components to the Ion Implanted Femoral Bearing Series

Proprietary Name:	LFIT™ V40™ Femoral Head Components
Common Name:	Femoral Head Component
Classification Name and Reference:	21 CFR §888.3350 Hip Joint Metal/ Polymer Semi-constrained Cemented Prosthe
Proposed Regulatory Class:	II
Device Product Code:	(87) JDI, LWJ, KWY
For Information contact:	Jennifer A. Daudelin, Regulatory Affairs Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677 (201) 934-4354 Fax: (201) 760-8435 Email: jdaudelin@howost.com

This Special 510(k) submission is intended to add the V40™ femoral head components to the Ion Implanted Femoral Bearing Series. The intended use, manufacturing methods, materials, packaging and sterilization of the subject device are identical to those of predicate devices. The predicate ion implanted femoral bearing components were found substantially equivalent via the 510(k) process in K910988. The V40™ femoral head components were cleared in 510(k) numbers: K936126, K950541, and K993601. The predicate ion implanted devices are cobalt chromium alloy femoral heads conforming to ASTM F1537. The V40™ femoral head components are also fabricated from cobalt chromium alloy conforming to ASTM F799. These devices have an outer diameter range from 22mm to 32mm with varying neck offsets. Like the predicate devices, the subject devices are intended for use with femoral stems and acetabular components in primary or revision total hip arthroplasty.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 11 2001

Ms. Jennifer A. Daudelin
Regulatory Affairs
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K010757
Trade Name: LFIT™ V40™ Femoral Heads
Regulatory Class: II
Product Code: JDI, LWJ, and KWY
Regulation: 21 CFR 888.3350
Dated: March 12, 2001
Received: March 13, 2001

Dear Ms. Daudelin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K010757

Device Name: LFIT™ V40™ Femoral Heads

Indications for Use:

These devices are modular components of a total hip system. These femoral heads are intended for use with femoral stems and acetabular components in primary or revision total hip arthroplasty.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010757